

health (PSH) profile, were analyzed. **RESULTS:** A total of 131 patients were included in the waiting-list and 80% received a kidney transplant, 41% were ECD. Sixty percent were men. The age difference between ECD, SCD and not transplanted was significant ( $p = 0.000$ ). The mean time in waiting-list (15 months) and cold ischemia time (14 hours) were the same for both groups. There were no differences in clinical variables. The PSH improvement in ECD at year was significant ( $p = 0.022$ ), whereas for the SCD not. There were differences in incomes ( $p = 0.041$ ) between groups. The survival at first year was 100% for SCD and 97.7% for ECD. At year, mean cost for SCD transplant was €54,343/year versus €59,136/year for ECD (no significant). The difference in QALYs between transplanted ones and not-transplanted was significant ( $p = 0.019$ ). The utility was: 0.8096 QALYs for SCD, 0.7786 for ECD and 0.6838 for not transplanted. Cost-utility analysis showed that one QALY in SCD cost €67.27€, versus €79.95€/QALY of ECD and €80.43€/QALY of not transplanted in waiting list. **CONCLUSIONS:** There were no clinical differences and not in PSH at the first transplant year between SCD and ECD, but there were in age and what it bears. The differences in terms of cost-utility, in the first year, between ECD and not transplanted were small. However, the differences could be important in long term, because after the first year the costs have an important decrease. Therefore, it seems that ECD transplant have a good results in health and costs.

#### PUK14

##### **A HEALTH ECONOMIC EVALUATION OF THE USE OF ERYTHROPOIESIS-STIMULATING AGENTS (ESA) IN PATIENTS WITH RENAL FAILURE TREATED WITH HAEMODIALYSIS**

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**OBJECTIVES:** To assess the cost and the resource use related to anaemia management with Aranesp®, Eprex® and Neorecormon(r) in patients with chronic renal failure treated with haemodialysis in Belgium; and to assess the effect of anaemia management on haemoglobin (Hb) levels. **METHODS:** Data on anaemia management and resource utilization were collected using a retrospective chart review conducted in 11 haemodialysis centres distributed across Belgium. From each centre between 30 and 40 patients were randomly selected. Data on drug use, transfusion, consultations, hospitalizations, diagnostic tests and Hb level were collected over a 1-year study period (1 December 2005 until 30 November 2006). The costs were calculated by multiplying each item of resource use with its unit cost (in 2007; in €) from the Belgian health care payer's perspective (RIZIV/INAMI). **RESULTS:** A total of 335 patients were included of which 105, 132 and 98 were treated with Aranesp®, Eprex® and Neorecormon(r), respectively. There were no demographic differences between the treatment arms. There were no statistically significant differences between the 3 ESAs in the total annual anaemia management cost in haemodialysis treated chronic renal failure patients despite differences in drug list prices between the 3 ESAs. The cost ranged from €8203 to €9281. There were no significant differences in the average weekly dose of ESA between the 3 drugs. Independent of the iron status of the patient, or when stratified by CRP level, the percentage of patients reaching a Hb level  $\geq 11$  g/dl was similar in the 3 treatment arms and ranged from 76% to 81%. **CONCLUSIONS:** In patients with chronic renal failure, treated with haemodialysis, there were no significant differences between the 3 available ESAs in medical resource use, average dose of ESA needed, annual anaemia management costs from the perspective of the Belgian public health care payer and in Hb control.

#### PUK15

##### **ASSESSMENT OF THE BENEFITS OF TIME SAVINGS ACHIEVED BY ONCE MONTHLY INJECTION OF ERYTHROPOIETIN STIMULATING AGENTS (ESA) ON ANAEMIA MANAGEMENT IN HAEMODIALYSIS CENTRES**

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**OBJECTIVES:** Due to their duration of action, current erythropoietin stimulating agents (ESA) require frequent administrations (up to 3 injections per week). The objective of this study was a) to estimate the potential time savings resulting from a switch to a new once a month CERA (continuous erythropoietin receptor activator), and b) to determine its benefits in quality of care and procedural improvements. **METHODS:** The different stages in the global ESA Hospital Process (from ordering to invoicing) were identified. A time and motion method was used for each stage to determine the time spent managing ESA in eight dialysis centres with different profiles. Simulations were performed to assess the time savings according to various levels of the new product's penetration rates. Qualitative interviews with the medical and administrative staff involved in the ESA management were carried out to assess the expected benefits of switching to monthly injections. Intermediary and final results were validated by a Scientific Committee. **RESULTS:** Current ESA management requires between 6 h 12 min and 20 h 36 min per patient per year. The estimated total time saved by switching to monthly injections ranged from 5 h 13 min to 17 h 29 min per patient per year. Pharmacists and nurses are the two staff categories most affected by the time savings, which are respectively from 28 min to 13 h and from 51 min to 3 h 32 m per patient per year. Qualitative interviews supported these results and also highlighted a potential time savings for administrative staff. **CONCLUSIONS:** Administration of a monthly CERA injection could reduce total time spent on ESA management by up to 85% (for a total conversion). Time saved would allow the staff involved to improve both their organisation and procedures (stock management, outdated products, etc.) and their quality of care (optimisation for Continuing Professional Development indicators: patient close monitoring, compliance, etc.).

##### **URINARY/KIDNEY DISORDERS— Patient-Reported Outcomes Studies**

#### PUK16

##### **EXPLORING THE IMPACT OF CHANGES IN NEUROGENIC URINARY INCONTINENCE FREQUENCY AND CONDITION SPECIFIC QUALITY OF LIFE ON PREFERENCE-BASED OUTCOMES**

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**OBJECTIVES:** Many trials do not measure Quality Adjusted Life Years (QALYs). Therefore decision analysts wishing to extrapolate trial results for policy makers often map condition specific outcomes to preference scores. We estimated the relationship between changes in preference scores and commonly reported condition specific outcomes in patients with neurogenic urinary incontinence (UI). **METHODS:** In 59 patients recruited to a neurogenic UI randomised controlled trial, clinical outcomes (UI

episodes), condition specific quality of life (Incontinence Quality of Life Questionnaire (I-QOL)), and SF-6D preference scores were measured at enrollment and 24 weeks after treatment with a single injection of botulinum toxin type A or placebo. We measured the correlation between SF-6D, I-QOL and UI episode change scores. We used multiple linear regressions to estimate the impact on SF-6D scores of 50%; 50%–99% and 100% reductions in UI episodes and a 10-point improvement in I-QOL. These thresholds are thought to be clinically significant and are often reported as trial outcomes. **RESULTS:** SF-6D change scores between enrollment and 24 weeks were moderately correlated with I-QOL change scores ( $\rho = 0.41$ ;  $p < 0.01$ ) but non-significantly correlated with UI episode changes scores ( $\rho = -0.19$ ;  $p = 0.20$ ). At 24 weeks, mean (95% CI) daily UI episodes fell by 0.85 (0.04, 1.3) and mean I-QOL scores improved by 18 (12, 24). SF-6D scores increased by 0.03 (0.003, 0.058), due, primarily, to improvements in the role limitations domains. A  $\geq 50\%$  reduction in UI episodes was achieved by 49% of patients and corresponded to a 0.09 (0.02, 0.16) SF-6D increase. A  $\geq 10$ -point increase in I-QOL was attained by 65% of patients and was associated with a 0.05 (–0.02, 0.12) SF-6D increase. **CONCLUSIONS:** These estimates provide preliminary data for decision analysts wishing to map UI outcomes to preference scores. The results demonstrate that clinically important changes in condition specific quality of life are reflected in SF-6D preference scores.

PUK17

#### ESTIMATING THE QUALITY OF LIFE IMPACTS OF TOLTERODINE AND TAMSULOSIN TREATMENT IN MEN WITH LOWER URINARY TRACT SYMPTOMS AND OVERACTIVE BLADDER

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**OBJECTIVES:** A randomized clinical trial (TIMES) demonstrated that combination therapy with tolterodine extended release (ER) plus tamsulosin for 12 weeks provides clinical benefits over monotherapy with either agent or placebo in men with moderate to severe lower urinary tract symptoms (LUTS) and overactive bladder. However, the TIMES study did not report the impact of these therapies on utility. We developed a statistical model to predict the utility and quality-adjusted life-years (QALYs) associated with the various TIMES therapies. **METHODS:** The statistical model was developed using urinary tract symptoms and quality of life (SF-12) data collected from 9416 males participating as part of a separate epidemiologic survey (EpiLUTS). The model was a multinomial regression, which predicted the level of responses to each of the 12 domains of the SF-12. The predictors were daytime and nighttime urinary frequency, urgency episodes, urge incontinence and International Prostate Symptom Scores (IPSS). This regression was then used to predict SF-12 scores of the TIMES patients, based on the observed mean symptoms values in this study. Next, based on published regression algorithms, these predicted SF-12 answers were transformed into EQ-5D utility scores, from which QALYs were calculated. **RESULTS:** IPSS score and number of urgency episodes in 24 hours had the strongest impact on overall utility, whereas nighttime and especially daytime micturition frequency had less impact. At week 12, utility scores for placebo, tolterodine monotherapy, tamsulosin monotherapy, and combination therapy were 0.657, 0.684, 0.679 and 0.701, respectively. Corresponding QALYs over 12 weeks were 0.143, 0.146, 0.146 and 0.148. Thus, combination therapy resulted in the highest incremental QALYs, saving 0.005 QALYs vs. placebo, 0.002 vs.

tolterodine, and 0.003 vs. tamsulosin. **CONCLUSIONS:** Combination therapy with tolterodine ER plus tamsulosin results in the highest predicted utility and QALY gains compared to placebo or monotherapy with either agent.

PUK18

#### VALIDATION OF THE URINARY SENSATION SCALE (USS)

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**OBJECTIVES:** To assess the validity of the Urinary Sensation Scale (USS) in women with overactive bladder (OAB) and men with OAB and prostate symptoms (OAB-BPH). **METHODS:** Data from 2 clinical trials of tolterodine treatment for OAB were used to assess the validity of the USS, a 5-point rating scale to assess the amount of urinary urgency associated with each urination. The USS ranges from “No feeling of urgency: I could continue activities until I chose to use the bathroom” to “Unable to hold; leak urine: I had a wetting accident before arriving at the bathroom.” The USS was administered with a daily bladder diary in the 2 trials. Two methods to evaluate the USS are to calculate a mean urgency score (Mean USS) of all voids or to sum all urgency ratings (Sum USS). Concurrent validity, discriminant validity, and responsiveness of the USS were assessed. **RESULTS:** Data from 580 men (Trial 1) and 331 women (Trial 2) were analyzed. Mean age was 65.2 (men) and 47.8 (women); in both studies, 70% were Caucasian. Correlations of USS scores with bladder diary variables were small to moderate and higher among Sum USS than Mean USS. Correlations among the USS with OAB-q, Perception of Bladder Condition (PBC), and Perception of Treatment Benefit (PTB) were moderate to strong and higher with Sum USS. Both the Mean and Sum USS significantly discriminated (all  $p < 0.001$ ) among all bladder diary variables (except men, nocturia and UUI) when grouped as improved/not improved as well as by the OAB-q, PBC, and PTB. Effect sizes for men and women respectively were –0.52 and –1.09 for Mean USS and –0.72 and –1.36 for Sum USS. **CONCLUSIONS:** The USS is a valid and highly responsive measure of urinary urgency in women with OAB and men with OAB-BPH.

PUK19

#### PSYCHOMETRIC EVALUATION OF THE KHQ IN TEN LANGUAGES

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**OBJECTIVES:** To evaluate the psychometric properties of 10 language versions of the King's Health Questionnaire (KHQ). **METHODS:** The KHQ, a 21-item instrument to assess health-related quality of life in patients with urinary incontinence and OAB, has been translated into numerous languages. Data from a multicenter, randomized, double-blind, placebo- and active-controlled trial of fesoterodine for OAB patients were analyzed to assess the psychometric properties of the KHQ in ten languages. Patients completed the KHQ at Baseline (BL) and Week 12 of treatment and bladder diaries for 3 days before each visit. Mean BL scores, Cronbach alphas, and subscale change scores were calculated for the KHQ in each language. **RESULTS:** Data from 839 patients were analyzed (Australia = 104; Bulgaria = 58; Czech Republic = 55; Estonia = 59; Germany = 59; New Zealand (NZ) = 82; Poland = 84; Romania = 66; Russia = 81; and South Africa = 191). Mean age was  $56.7 \pm 13.9$  years; 80% were female; 96% were white. BL subscale scores ranged from 16.8 (General Health Perceptions [GHP]; NZ English) to 83.6 (Impact on Life; German). Six of 7 multi-item KHQ subscales (Role